Infections
Leishmaniasis
Project Summary

Title: Development of a Leishmania Skin Test Antigen (LSTA)

Synopsis: This study continues development of a skin test for leishmaniasis (like the skin test for tuberculosis) that would help diagnose this parasitic infection in Gulf War veterans and others who may have been exposed.

Overall Project Objective: Develop an intradermal skin test for the screening of U.S. Service members who may have been exposed to Leishmania parasites during deployments to leishmaniasis endemic areas.

Status/Results to Date: As reported last year, the lyophilized LSTA was reformulated into a liquid product to avoid a suspected hypersensitivity to a component of the lyophilization buffer. A new IND for this reformulated liquid Microfluidized-lysate (MFL)-LSTA was submitted to the FDA in 1999. A Phase I clinical trial was conducted in 15 healthy volunteers which demonstrated safety of the product by showing no significant local or systemic reactions to the product. Additionally, the product was administered in increasing dose and demonstrated that the skin test antigen had no significant local or systemic side effects when used at the planned maximal dose. A RFP was released to identify a commercial manufacturer for the future licensure of the LSTA product. A contract was awarded and phase I/II dose ranging and potency trials are underway.

Project:	DoD-8B
Agency:	Department Of Defense
Location:	Walter Reed Army Institute of Research
P.I. Name:	D. Scott Doughty
Research Type:	Development
Research Focus:	Leishmaniasis
Focus Category:	Infections
Status:	Ongoing
Study Start Date:	October 01,1993
Estimated Completion Date:	January 31,1999

Specific Aims: The goal is to identify a safe, potent, and non-sensitizing Leishmania Skin Test Antigen (LSTA); manufacture it under cGMP; obtain an IND for its use in phase I, II, and III clinical trials; and obtain ultimately a commercially available, FDA-licensed product.

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Methodology: Skin tests are widely accepted diagnostic interventions for diagnosis of prior infection with an infectious agent (e.g., tuberculosis). Currently there is no Leishmania skin test licensed for use in the USA. Once required phase I and phase II studies are completed in humans, studies could be performed in Gulf War veterans with confirmed and suspected leishmaniasis.

Most Recent Publications:

None to date.

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